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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,064	12/04/2001	Michael Campbell	MBHB00-1257-B	9564

7590

12/03/2002

A. Blair Hughes
McDonnell Boehnen Hulbert & Berghoff
32nd Floor
300 S. Wacker Drive
Chicago, IL 60606

EXAMINER

RAO, DEEPAK R

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 12/03/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/005,064

Applicant(s)
Campbell et al.

Examiner
Deepak Rao

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 20, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-13, 28-36, 38-47, 62, and 63 ☒ are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 28-36, 38-47, 62, and 63 ☒ are rejected.
- 7) ☒ Claim(s) 3-13 ☒ are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 6) ☐ Other:

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DETAILED ACTION

This office action is in response to the amendment filed on September 20, 2002.

Claims 1, 3-13, 28-36, 38-47, 62 and 63 are pending in this application.

Election/Restriction

As indicated in the previous office action, the examination was limited to a subgenus around the elected species. Applicant's amendment excluded the reference compounds and therefore, as per the guidelines of MPEP § 803.02, the search was expanded to compounds of formula I wherein Z is N, retaining all the other definitions as indicated in the previous office action (see paper no. 4, page 5), and art was found.

The following rejections are withdrawn:

The rejections under 35 U.S.C. 112, second paragraph of the previous office action are withdrawn in view of the amendments.

The rejection under 35 U.S.C. 102(b) of the previous office action is withdrawn in view of the amendment.

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The following rejections are necessitated by the amendment:

Claim Rejections - 35 U.S.C. § 112

Claims 28-35 and 38-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. Claims 28, 30, 32 and 34 are drawn to 'a method for treating.... administering.... a **compound of claim 1**', however, claim 1 is also drawn to "a method of treating" and not to a compound. Therefore, the claims as amended are improperly dependent on claim 1 because the claims are drawn to different methods.
2. Claim 38 depends from a canceled claim 37.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 28-35, 36 and 62-63 are rejected under 35 U.S.C. 102(a) as being anticipated by Moriarty et al., WO 01/47897 (published July 5, 2001). The instantly claimed compounds

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and the methods of use read on the reference disclosed compounds and the use thereof. See formula I in page 3 and the use of the compounds in pages 14-16 wherein the compounds are disclosed to be useful in the treatment of atherosclerosis. The instant claims read on the prior art taught therapeutic effect because the instant claims are drawn to administration of the prior art compounds, in same dosages, to the same population. The therapeutic effect of claim 1 is evident from page 2 of the specification and the therapeutic effects of claims 28, 30, 32 and 34 is evident from the respective dependent claims. The prior art also teaches that the compounds are useful in the treatment of the instantly claimed disease, namely atherosclerosis (see page 16, line 5) and therefore, the instantly claimed mechanism of sodium channel modulation is inherently taught in the reference.

Note: Applicant can not rely on the benefit of priority based on Provisional Application 60/251,916 (filed December 7, 2000) because the prior application does not fully support the instantly claimed invention. The prior application does not disclose the instant Formula I and the corresponding compounds.

2. Claims 1 and 28-35 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 1,384,684 (cited in PTO-892 of paper no. 4). The instantly claimed methods of use of compounds of formula I read on the use taught for the reference disclosed compounds, see formula (I) in page 1 and the utility in page 2, lines 25-26.

3. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Kozakiewicz, Chem. Abstract 130:267406 (1999). The instantly claimed compounds read on the reference disclosed

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compounds, see the compound having RN 222418-76-0 in the enclosed copy of the CAPLUS computer search report.

4. Claims 36 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Pomarnaka et al., Chem. Abstract 130:153642 (1998). The instantly claimed compounds read on the reference disclosed compounds, see e.g., the compound having RN 201229-87-0 in the enclosed copy of the CAPLUS computer search report.

5. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Kelarev et al., Chem. Abstract 130:68841 (1998). The instantly claimed compounds read on the reference disclosed compounds, see the compound having RN 213697-64-4 in the enclosed copy of the CAPLUS computer search report.

6. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Silin et al., Chem. Abstract 129:260428 (1998). The instantly claimed compounds read on the reference disclosed compounds, see the compound having RN 213697-59-7 in the enclosed copy of the CAPLUS computer search report.

7. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Dollinger et al., Chem. Abstract 128:270618 (1998). The instantly claimed compounds read on the reference disclosed compounds, see the compounds having RN 205532-34-9 and 205532-38-3 (page 27) in the enclosed copy of the CAPLUS computer search report.

Note: A complete search for the subgenus of formula I wherein Z is NR5 could not be performed, a representative number of references are used in the above rejections.

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Allowable Subject Matter

Claims 3-13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 38-44 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.


Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Deepak Rao
Primary Examiner
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December 2, 2002